REMARKS

Claims 1-2, 5-8, 10-13, and 15-23 are pending in the application. The amendments to the claims serve to further clarify the present invention. Support for "aeration hole" in the amended claims 1 and 13 can be found at page 5 in the specification. Support for "coated with silica gel, a molecular sieve, or a desiccant" in the amended claims 5-7 can be found at page 5 in the specification. Support for new claims 22-23 can be found at page 1 in the specification. It is believed that no new matter has been inserted into the application. Accordingly, entry of the amendments to the application is respectfully requested.

Rejection Under 35 U.S.C. § 102(b) Over Joslin (U.S. Patent No. 4,353,868)

Claims 1, 2, 5-9, 12, 13 and 19-21 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Joslin. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants assert that the presently claimed invention is distinguished from Joslin.

Presently claimed invention

The presently claimed invention is directed to a device for biological sample collection and storage. The samples, liquid or solid, collected by the inventive device may be stored for long periods of time with minimal degradation so that the biological material is substantially intact to be analyzed. The presently claimed invention is also directed to collecting samples comprising only a minimal amount of the biological molecules to be analyzed.

Joslin

Joslin discloses a specimen collecting device including a swab and a reservoir containing a quantity of a liquid specimen preserving or sustaining medium. Joslin's device is

characterized by the swab attached to the cap, which can be used as a handle for the swab. The specimen collected using the device of Joslin is a culture from a patient's body. The swab in Joslin's device is used to apply the collected specimen to a microscopic slide or to a dish for incubation. Further, it is believed that Joslin's device is used to maintain the microorganisms in the culture specimen collected from the patients. To preserve the microorganisms in viable form, the specimen carrying swab in Joslin's device is continuously held in contact with the pad and the swab tip remains wet or soaked by the liquid culture-sustaining medium. The liquid culture media used in Joslin are Stuart's modified media, or a liquid culture of bile, blood or egg (Col. 5, lines 22-25). According to BioChemika for microbiology (from Sigma-Aldrich's catalog), Stuart's modified media or transport medium is used for the storage and transport of swab specimen of a wide variety of pathogenic microorganisms including *Neisseria*, with extensive conservation of the accompanying flora composition. It is well-known in the art that bile, blood or egg is added to the liquid culture media to promote growth of particular types of bacteria. It is believed that the kind of culture medium for the Joslin's device is chosen on the basis of the type of culture to be preserved or cultured. However, Joslin fails to disclose or suggest a device comprising a pad or storage area comprising chemical preservatives or enzyme inhibitors that are designed to inhibit the growth of cells as in the presently claimed invention.

Distinctions of the presently claimed invention over Joslin

First of all, the protrusion in the presently claimed invention is attached to the body of the inventive device, not to the cap. The samples to be collected with the presently claimed invention is not the whole cell or microorganisms, but any biological samples that contain a minimal amount of intact biological molecules which can be analyzed after collection and storage in the device. The chemical preservative or enzyme inhibitor disclosed in the

presently claimed invention is used as an inhibitor of microbiological growth and degradative enzymes such as proteases. Therefore, these preservatives or enzyme inhibitors are necessary to keep the biological samples in substantially intact form, minimizing degradation of the samples and for long-term storage of the samples collected by the inventive device. The chemical preservatives or enzyme inhibitors disclosed in the presently claimed invention are well known in the art as inhibitors of microbiological contamination and includes among others, DNase inhibitors, EDTA, buffers, sodium azide, sodium benzoate, procline, and thimerosal.

Contrary to the presently claimed invention, Joslin discloses a device, wherein the protrusion with a swab is connected to the cap of the device. In further contrast to the presently claimed invention, Joslin discloses use of liquid culture-sustaining medium to promote the growth of culture or particular types of microorganisms, rather than inhibiting microbiological growth as in the presently claimed invention.

In the Advisory Action dated July 11, 2005, the Examiner re-asserts that the presently claimed invention is anticipated by Joslin because Joslin discloses a pad comprising a chemical preservative. Applicants disagree. As mentioned above, among several distinctions between the presently claimed invention and Joslin, the chemical preservative that the Examiner refers to is actually culture medium, not a chemical preservative or enzyme inhibitor as in the presently claimed invention. Therefore, the presently claimed invention is distinguished from the device disclosed in Joslin. Accordingly, it is believed that Joslin fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. § 102(b) Over McClintock (U.S. Patent No. 5,980,828)

Claims 1, 2, 5, 8 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by McClintock. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants assert that the presently claimed invention is distinguished from McClintock.

McClintock

McClintock discloses an assay device for rapid and sensitive detection of bacteria. The assay device disclosed in McClintock is a flat plate-like assay device to detect chemiluminescence. Further, the device is used to measure adenosine triphosphate (ATP) to indirectly measure the bacterial content by collecting the suspected sample with the collection pad and moving the sample to the reading portion containing chemiluminescent reagents by folding the collecting arm comprising the collection pad to touch the reading portion. However, McClintock fails to disclose or suggest a device comprising a pad or storage area comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention.

Distinctions of the presently claimed invention over McClintock

First of all, the device disclosed in McClintock has a flat geometry contrary to non-flat shape of the presently claimed invention. The device disclosed in McClintock also lacks an aeration hole which is included in the inventive device. Chemiluminescent reagents disclosed in McClintock, for example, hydrogen peroxide, horseradish peroxidase, luminal, diacylhydrazides, acridinium salts, dioxitanes, nicotine adenine dinucleotide, luciferase, are related to chemiluminescence chemistries and are irrelevant to the preservatives or enzyme inhibitors recited in the instant claims. The chemiluminescent reagents in McClintock are used for chemiluminescent reaction to detect ATP and indirectly measure bacterial content. Further, the bacteriolytic agents disclosed as carrier liquids in McClintock, including buffer

solutions of TRIS, HEPES buffers with EDTA and detergents such as Triton X-100, Nonidet P40, n-Undecyl Beta-D glucopyranoside, Zwitterionic detergents and cationic detergents, are used to open bacterial cells and liberate cell components including ATP.

In the Advisory Action dated July 11, 2005, the Examiner re-asserts that the presently claimed invention is anticipated by McClintock because McClintock discloses a pad comprising chemical preservatives or enzyme inhibitors and use of Triton X-100 as protein inhibitor. Applicants disagree. As mentioned above, among several distinctions between the presently claimed invention and McClintock, the chemical preservatives that the Examiner refers to are actually chemiluminescent reagents and bacteriolytic agents including buffers and detergents, not a chemical preservative or enzyme inhibitor as in the presently claimed invention. Further, it is well-known in the art that Triton X-100 is often used as a detergent in protein extraction from the cells and the role of Triton X-100 is to open cells and liberate cell components as disclosed in McClintock. Therefore, the presently claimed invention is distinguished from the device disclosed in McClintock. Accordingly, McClintock fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. § 103(a) Over Dechow in view of Bull (U.S. Patent No. 5,275,953)

Claims 13 and 17 have been rejected under 35 U.S.C. § 103(a) as being obvious over Dechow in view of Bull. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Dechow

Dechow discloses a device for collecting samples. However, Dechow fails to disclose or suggest a device comprising at least one aeration hole and a storage area coated with a chemical preservative or enzyme inhibitor as in the presently claimed invention.

Bull

Bull discloses a blood extracting and receiving container assembly. However, Bull fails to disclose a device comprising at least one aeration hole and a storage area coated with a chemical preservative or enzyme inhibitor as in the presently claimed invention.

Distinctions of the presently claimed invention over the cited references

Dechow is cited for the disclosure of a device for collecting samples including at least one collection protrusion comprising at least one tip, at least one pad for contacting the tip, and a storage area, which is fitted with tubing. However, Dechow fails to disclose a device comprising at least one aeration hole and a storage area coated with a chemical preservative or enzyme inhibitor as in the presently claimed invention.

Bull discloses a coating agent, which the Examiner has interpreted to mean a chemical preservative or enzyme inhibitor. However, the coating agent disclosed in Bull is an ionic radiographic contrast agent including ionic contrast agent formed from single benzene rings, a dimerized ionic contrast agent having two benzene rings and inhibits activation of both platelets and blood clotting factors, which prevents initiation of blood clotting processes (Col. 5, lines 21-66). Thus, the coating agent disclosed in Bull is not a chemical preservative or enzyme inhibitor as in the presently claimed invention. Therefore, Bull also fails to disclose or suggest a device comprising at least one aeration hole and a storage area comprising chemical preservatives or enzyme inhibitors. Therefore, Bull fails to remedy the deficiencies in the Dechow reference. Accordingly, the presently claimed invention is not obvious over the cited references.

Rejection Under 35 U.S.C. § 103(a) Over Dechow in view of Bull and Bazell (U.S. Patent No. 4,370,987)

Claims 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious over Dechow in view of Bull and Bazell. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Dechow and Bull are discussed above.

Bazell

Bazell discloses a medical fluid collection system including a double ended needle. However, Bazell fails to disclose a device comprising at least one aeration hole and a storage area coated with a chemical preservative or enzyme inhibitor as in the presently claimed invention.

Distinctions of the presently claimed invention over the cited references

Dechow and Bull fail to disclose a device comprising at least one aeration hole and a storage area comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention. Bazell is cited by the Examiner for its disclosure of a syringe having a unidirectional piston. However, Bazell fails to disclose or suggest a device comprising at least one aeration hole and a storage comprising chemical preservatives or enzyme inhibitors, and therefore fails to remedy the deficiencies in the Dechow and Bull references. Accordingly, the presently claimed invention is not obvious over the cited references.

Rejection Under 35 U.S.C. § 103(a) Over Dechow in view of Bull and Erickson (U.S. Patent No. 6,602,205)

Claim 18 has been rejected under 35 U.S.C. § 103(a) as being obvious over Dechow in view of Bull and Erickson. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Dechow and Bull are discussed above.

Erickson

Erickson discloses an apparatus for collecting a sample of body fluid located within the dermal layer. However, Erickson fails to disclose a device comprising at least one aeration hole and a storage area coated with a chemical preservative or enzyme inhibitor as in the presently claimed invention.

Distinctions of the presently claimed invention over the cited references

Dechow and Bull fail to disclose a device comprising at least one aeration hole and a storage area comprising chemical preservatives or enzyme inhibitors as in the presently claimed invention. Erickson is cited by the Examiner for its disclosure of a capillary tubing. However, Erickson fails to disclose or suggest a device comprising at least one aeration hole and chemical preservatives or enzyme inhibitors, and therefore fails to remedy the deficiencies in the Dechow and Bull references. Accordingly, the presently claimed invention is not obvious over the cited references.

Rejection Under 35 U.S.C. § 103(a) Over Joslin in view of Sak (U.S. Patent Application Publication No. 2002/0161313)

Claims 10 and 11 have been rejected under 35 U.S.C. § 103(a) as being obvious over Joslin in view of Sak. Applicants traverse this rejection. Reconsideration and withdrawal of this rejection is respectfully requested.

Joslin is discussed above.

Sak

Sak discloses an apparatus for sampling cervical tissue. However, Sak fails to disclose a device comprising at least one aeration hole and a storage area coated with a chemical preservative or enzyme inhibitor as in the presently claimed invention.

Distinctions of the presently claimed invention over the cited references

Joslin fails to disclose a device comprising at least one aeration hole and chemical preservatives or enzyme inhibitors as in the presently claimed invention. Sak is cited by the Examiner for its disclosure of written instructions on using a device for collecting biological samples. However, Sak also fails to disclose or suggest a device comprising at least one aeration hole and chemical preservatives or enzyme inhibitors, and therefore fails to remedy the deficiencies in the Joslin reference. Accordingly, the presently claimed invention is not obvious over the cited references.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. **502486** for any fees required under 37 CFR § 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. **502486**.

Respectfully submitted,

JHK Law

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